CIC

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,938	06/04/2002	Shinichiro Morita	SAEG108.001APC	4758

20995 7590 05/17/2005

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,938	MORITA ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 2/11/05 in response to an office action of 9/8/04 added new claims 12-14.

Claims examined on the merits are 1-14, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,863,531) in view of Vyakarnam et al (6,534,084 B1) taken with Hinsch et al (EP 0 274 898) and Japanese patent 3-23864 for reasons in the previous office action of 9/8/04, and for reasons herein.

The claims are drawn to a matrix for culturing cardiovascular cells to regenerate cardiovascular tissue comprising a sponge made of a bioabsorbable material and a reinforcement made of a bioabsorbable material. Also claimed is a method of culturing cardiovascular cells to regenerate cardiovascular tissue by seeding cells on the matrix and culturing the cells. The sponge has a pore diameter of about 5-100 μm. The matrix can be in the form of a vascular prosthesis seeded with a cell culture and cultured *in vitro*. The cell culture can be a mixture of two or more different kinds of cells. The matrix surface of the prosthesis can be completely covered with cells.

Naughton et al disclose producing tissue *in vitro* by seeding cells on a three-dimensional structure having interstitial spaces

which can be used to form tubular tissue structures (col 6, lines 55-60 and col 22, line 41) such as in the form of blood vessels (col 24, line 33), arteries (col 24, line 37) or veins (col 25, line 24). The three dimensional structure can be made of biodegradable material such as polyglycolic acid, polylactic acid or polyglycolic acid copolymer (col 9, lines 60-62). The three-dimensional structure can be made of a sponge (col 9, line 42).

Vyakarnam et al disclose foam structures that can be composed of copolymers of lactide such as a poly(L) lactide-co-E-caprolactone (col 6, line 45, col 9, lines 53-55 and col 12, lines 5-9), and which can be used to regenerate tissue such as tubular structures such as vascular grafts (col 3, lines 1 and 20-21, and col 9, lines 19-24). The pore size of the foam can be 30-50 Tm or 100-200 Tm (paragraph bridging cols 4 and 5). The foam can be reinforced with fibers (col 6, line 40).

Hinsch et al disclose a porous implant having a pore size of 10-200 Tm for the growth of blood vessels in the form of a foam made of a resorbable polymer such as a copolymer of glycolide and lactide (page 4, lines 1-8). The foam may contain textile reinforcing elements such as fibers or knitted fabrics (page 3, lines 8-13).

The Japanese patent discloses a reinforced collagen sponge for implanting in tissue. The sponge is reinforced with fibers made of poly-L-lactic acid.

It would have been obvious to form the biodegradable polyglycolic acid copolymer tubular structures of Naughton et al with the biodegradable foam of Vyakarnam et al that is a copolymer of glycolide and lactide since this foam can be used for producing a tubular structure and has advantageous properties. It would have been further obvious to reinforce the foam with fibers as suggested by Hinsch et al and the Japanese patent using fibers to reinforce a foam implant. It would have been obvious to use fibers formed of poly-L-lactic acid as taught by the Japanese patent so thqt both the foam and fibers are bioabsorbable. Using polyglycolic acid as in claim 4 to form the fibers would have been a matter of obvious choice. A foam as disclosed by the references is a sponge. When forming the tubular structures of Naughton et al, cardiovascular cells are used and the tissue produced is cardiovascular tissue. The conditions of dependent claims would have been obvious from the disclosures of the references. Structures other than tubular structures such as a cardiac valve or pericardium as in certain dependent claims would have been obvious from the many different structures disclosed by Naughton et al. A vascular prosthesis as in claim 12 would have been obvious from Naughton et al disclosing a tubular structure in the form of blood vessels, arteries or veins. Using two or more different cells as in claims 11 and 12 would have been obvious from Naughton et al using different types of cells together. Cells completely covering the matrix as in claim 14 is inherent with producing a tubular structure as taught by Naughton et al.

Response to Arguments

Applicant's arguments filed 2/11/05 have been fully considered but they are not persuasive.

Applicants urge that Naughton et al and Vyakarnam et al are drawn to tissue engineering, and are totally different from Hinsch et al and the Japanese patent which do not employ tissue engineering, and there is no motivation to combine the teachings of Naughton et al and Vyakarnam et al with those of Hinsch et al and the Japanese patent. However, since the foam of Vyakarnam et al, which is used for tissue engineering can be reinforced with fibers, it would have been apparent that reinforcement is important irrespective of whether tissue is produced on the foam or sponge before implanting. Even after tissue is engineered on the foam or sponge, it is implanted and reinforcement would have been expected to be important for the same type of reasons as when tissue is not produced on the foam or sponge before implanting. Moreover, the invention of claims 1-6 does not require tissue to be present, and the matrix can be implanting without seeding with cells and culturing to produce tissue.

As to claims 3-5 that applicants urge are not disclosed by the references, Vyakarnam et al disclose foam structures composed of poly(L) lactide-co-E-caprolactone, and the Japanese patent discloses a sponge reinforced with fibers made of poly-L-lactic acid. It would have been well within the skill of the art to use the foam of Vyakarnam et al in Naughton et al and reinforce the foam with the fibers of the Japanese patent. The use of polyglycolic acid for

reinforcement as in claim 4 would have also be obvious since this polymer would have been expected to provide the same function as polylactic acid when used to make fibers.

The results in Example 1 are unpersuasive, since the references suggest using fibers to reinforce tubular structures to be implanted, and it would have been obvious to reinforce the vessel before implanting. The references would not have taught reinforcement if reinforcement had not needed to provide additional strength.

As to claims 12-14, Naughton et al, as well as Vyakarnam et al, suggest seeding and culturing on a matrix to be implanted. The references are combined together and must be considered as whole in combination rather than each alone.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
5/16/05